

### **Remarks**

Applicants have received and reviewed the Final Office Action mailed July 15, 2008 and the Advisory Action mailed October 6, 2008. A Notice of Appeal and Pre-Appeal Brief Request were filed on October 15, 2008. A Notice of Panel Decision from Pre-Appeal Brief Request was mailed on December 8, 2008 resetting the time for filing an Appeal Brief. Currently, claims 17, 19, and 39-62 are pending, of which all stand finally rejected. With this Amendment, claims 17, 42-45, 47, 57, and 61 have been amended, claims 41 and 62 have been canceled without prejudice, and newly presented claim 63 has been added. Reconsideration and reexamination are respectfully requested.

#### ***Claim Rejections - 35 U.S.C. §112***

On page 2 of the Final Office Action, claims 47-56 and 62 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner states, "At the time the application was filed, the applicant failed to disclose that after expansion of the bulge portion, 'a portion of the bulge portion is positioned within the circumferential plane'". While Applicants must respectfully disagree, in the spirit of cooperation, Applicant has deleted the phrase "a portion of the bulge portion is positioned within the circumferential plane" from claims 47 and 62. Therefore, claims 47-56 and 62 are believed to comply with the written description requirement of § 112, first paragraph, and withdrawal of the rejection is respectfully requested.

#### ***Claim Rejections - 35 U.S.C. §103***

On page 3 of the Final Office Action, claims 17, 19, 39, 40, 46, 57, 58, and 61 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi et al. (US 6,325,826). After careful review, Applicants must respectfully traverse the rejection.

Turning to claim 17, which recites:

17. (Currently Amended) A system comprising:

only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a bulge region configured to protrude radially outward from the body region when expanded, the bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the bulge region extending less than the entire circumference of the body region, wherein the bulge region is configured to have different pressure and/or inflation characteristics than the elongate body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, each of the moveable members being moveable independent of the other moveable members, the stent body being expandable from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body, in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and aligned with the bulge region of the single balloon, and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall by the expansion of the bulge region of the single balloon to form a scaffold, the scaffold defining a side opening in the stent wall.

Without conceding the correctness of the Examiner's rejection, Applicant has amended claim 17 to include elements of claim 41, as well as other elements. Claim 41 has been canceled without prejudice. Nowhere does Lam or Vardi et al., either alone or in combination, appear to teach or suggest, at least, "only a single catheter, the single catheter having only a single balloon", "wherein the single balloon includes an elongate body region having a bulge region configured to protrude radially outward from the body region when expanded, the bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the bulge region extending less than the entire circumference of the body region, wherein the bulge region is configured to have different pressure and/or inflation characteristics than the elongate body region" and "in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and aligned with the predefined bulge region of the single balloon, and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall by the expansion of the predefined bulge region of the single balloon to form a scaffold, the scaffold defining a side

opening in the stent wall”, as recited in claim 17. Thus, amended claim 17 is believed to be patentable over Lam in view of Vardi et al. For similar reasons and others, claims 19, 39, 40, and 46, which depend from claim 17 and include additional limitations, are believed to be patentable over Lam and Vardi et al. and withdrawal of the rejection is respectfully requested.

Turning to claim 57, which recites:

57. (Currently Amended) A catheter system comprising:  
a catheter having an balloon arrangement, the balloon arrangement including an elongate body portion; and  
a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, the movable members configured as self expandable structures that move from an unexpanded position retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall, wherein when activated by expansion of the stent wall causes the movable members to move from the unexpanded position to the expanded position, at least a portion of the moveable members expanding towards a proximal end of the stent body and at least a portion of the moveable members expanding towards a distal end of the stent body.

Nowhere does the combination of Lam and Vardi et al. appear to teach or suggest “wherein expansion of the stent wall causes the movable members to move from the unexpanded position to the expanded position”, as recited in claim 57.

Instead, both Lam and Vardi et al. appear to teach the use of a balloon to expand the “movable member”. Nothing in Lam or Vardi et al. appears to teach or suggest the expansion of the stent wall causes the movable members to move from the unexpanded position to the expanded position. Therefore, for at least these reasons, claim 57 is believed to be patentable over Lam and Vardi et al. For similar reasons and others, claim 58, which depends from claim 57 and includes additional limitations, is believed to be patentable over Lam and Vardi et al. and withdrawal of the rejection is respectfully requested.

Turning to claim 61, which recites:

61. (Currently Amended) A catheter system, comprising:  
only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a predefined bulge region configured to protrude radially outward from the body region when expanded, the predefined bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of

the body region, the predefined bulge region extending less than the entire circumference of the body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall and movable between an unexpanded position within the circumferential plane and an expanded position extending radially outward from the circumferential plane to define an aperture in the circumferential wall, the single balloon extending within the stent body from at least a distal end to at least a proximal end of the stent wall, the stent wall being expandable by expansion of the body region of the single balloon and the movable members being expandable by expansion of the predefined bulge region of the single balloon, wherein a first moveable member extends radially outward at a location distal of the aperture in the circumferential wall and a second moveable member extends radially outward at a location proximal of the aperture.

With this Amendment, claim 61 has been amended to recite “wherein the single balloon includes an elongate body region and a predefined bulge region configured to protrude radially outward from the body region when expanded, the predefined bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the predefined bulge region extending less than the entire circumference of the body region”. Nowhere does Lam and Vardi et al. appear to teach or suggest at least these limitations. Therefore, for at least the reasons, claim 61 is believed to be patentable over Lam and Vardi et al.

On page 4 of the Final Office Action, claims 41-45, 59 and 60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi et al. (US 6,325,826), and further in view of Crocker et al. (US 5,843,116). After careful review, Applicants must respectfully traverse the rejection. For similar reasons discussed above, as well as others, claims 42-45, 59, and 60, which depend from one of claims 17 and 57 and include additional limitations, are believed to be patentable over Lam, Vardi et al., and Crocker et al. and withdrawal of the rejection is respectfully requested.

On page 5 of the Final Office Action, claims 47-56 and 62 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi et al. (US 6,325,826) in view of Marotta et al. (US 6,261,305). After careful review, Applicants must respectfully traverse the rejection.

Turning to claim 47, which recites:

47. (Currently Amended) A catheter system comprising:  
a catheter having a balloon arrangement, the balloon arrangement

including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded, the bulge portion being positioned at a location between a proximal end and a distal end of the body region and positioned at a predetermined circumferential location around a circumference of the body region, the bulge portion extending around less than an entire circumference of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, at least one of the moveable members being separate from the other moveable members, the stent wall being expandable from an unexpanded condition to an expanded condition by expansion of the body portion of the balloon arrangement, and the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent, wherein the bulge portion is positioned within the circumferential plane prior to expansion of the bulge portion, and after expansion of the bulge portion a portion of the bulge portion ~~is positioned within the circumferential plane and a portion of the bulge portion extends radially through the side opening outside the circumferential plane.~~

Nowhere do Vardi et al. or Marotta et al. appear to teach or suggest “the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded”, “wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region”, and “the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent”, as recited in claim 47. Therefore, for at least these reasons, claim 47 is clearly patentable over Vardi et al and Marotta et al. For similar reasons and others, claims 48-56, which depend from claim 47 and include additional limitations, are clearly patentable over Vardi et al and Marotta et al. and withdrawal of the rejection is respectfully requested.

Further, with this Amendment, claim 62 has been canceled without prejudice. As such, the rejection of claim 62 is rendered moot.

***Newly Presented Claim***

With this Amendment, Applicant has added newly presented claim 63. For similar reasons discussed above, as well as others, claim 63 is believed to be patentable over the cited references.

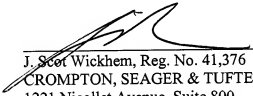
***Conclusion***

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: \_\_\_\_\_

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